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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/441,493 11/17/99 LENHARD

J PU3571US

EXAMINER

023347 HM12/0925  
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ART UNIT

PAPER NUMBER

1645  
DATE MAILED:

09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/441,493

Applicant(s)

LENHARD ET AL.

Examiner

Robert A Zeman

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 9-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 + 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group 3 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the Restriction Requirement (Paper No. 6) does not explain how the inventions of Groups I, II and III are independent. This is not found persuasive because, as detailed in Paper No. 6, "the different inventions are drawn to differing methods having different steps and leading to differing results " (see second paragraph).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-12 are pending. Claims 1-8 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 9-12 are currently under examination.

### ***Information Disclosure Statement***

The information disclosure statements filed on 9-15-2000 (Paper No. 4) and 6-7-2001 (Paper No. 9) are acknowledged and have been considered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of determining the temperature of internal tissues or organs comprising replacing a portion of skin in a region of the body in proximity to the tissue or organ with an infrared-invisible polymer and measuring said temperature using infrared thermography **in mice**, does not reasonably provide enablement for methods of determining the temperature of internal tissues or organs comprising replacing a portion of skin in a region of the body in proximity to the tissue or organ with an infrared-invisible polymer and measuring said temperature using infrared thermography **in any subject other than mice**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification provides examples of mice having portions of their skin removed (peeled back) and replaced with an infrared-invisible polymer (see figures 26 and 28-30). However, the specification is silent on how to use the claimed method on any subject that is not a mouse. The specification provides no guidance as to the area of skin that must be replaced relative to the size of the subject, whether said area is dependent on the physical characteristics (i.e. size, percent body fat, presence of fur etc.) of the subject or the effect of bone, cartilage, and muscle mass on infrared thermography. Additionally, the specification is silent on the effect adipose tissue; cartilage, muscle and bone have on the required "proximity" of the replacement site to the tissue/organ of interest? Consequently, one of skill in the art would not be able to use the invention commensurate in scope with the claims.

Claims 9-12 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is rendered vague and indefinite by the use of the term "portion". What area of skin must be replaced? Is it a percentage of the total area available or a set size? As written it is impossible to determine the metes and bounds of the claimed invention.

Claim 9 is rendered vague and indefinite by the use of the term "proximity". How close to the tissue/organ must the replacement area be? What is the maximum distance? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 10 is rendered vague and indefinite by the use of the phrase "before and after the administration of a test agent". How long before? How long after?

Claim 10 is rendered vague and indefinite by the use of the phrase "wherein a difference in temperature resulting from the administration of a test agent indicates that the test agent had a thermodynamic effect". Is Applicant asserting that act of administering said agent or the biological effect of the test agent causes the change in temperature? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 11 is rendered vague and indefinite by the phrase "one or more dosages of the test agent". Are said dosages administered simultaneously or over time? If administered over time, at what intervals?

Claim 12 is rendered vague and indefinite by the use of the phrase "measured at one or more time points after administration of test agent". How long after? At what interval? As written, it is impossible to determine the metes and bounds of the claimed invention.

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*Conclusion*

No claim is allowed.

Claims 9-12 are free of the art of record since no other method of infrared thermography includes the step of replacing a portion of skin with an infrared-invisible polymer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7911.

The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
DONNA WORTMAN  
PRIMARY EXAMINER

Robert A. Zeman  
September 24, 2001